

## **Package leaflet: information for the user**

### **cinfatos complex oral suspension**

Paracetamol/Dextromethorphan hydrobromide/Pseudoephedrine hydrochloride

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 5 days, in adults.

#### **What is in this leaflet:**

1. What cinfatos complex is and what it is used for
2. What you need to know before you take cinfatos complex
3. How to take cinfatos complex
4. Possible side effects
5. How to store cinfatos complex
6. Contents of the pack and other information

#### **1. What cinfatos complex is and what it is used for**

**Cinfatos complex** is a combination of paracetamol, dextromethorphan and pseudoephedrine.

Paracetamol belongs to the group of medicines called Non-Steroidal Anti-Inflammatories (NSAIDs), so it is effective for reducing pain and fever.

Dextromethorphan has a cough suppressant action (it inhibits the cough reflex).

Pseudoephedrine is effective in reducing nasal congestion.

It is indicated for symptomatic relief of influenza and the common cold with slight or moderate pain, fever, non-productive cough (irritative cough, nervous cough), and nasal congestion for adults and adolescents aged over 12 years.

You must talk to your doctor if you do not feel better or if you feel worse after 5 days of treatment.

#### **2. What you need to know before you take cinfatos complex**

This medicine can lead to dependence. Therefore treatment must be short-term.

#### **Do not take cinfatos complex:**

- If you are allergic (hypersensitive) to paracetamol, dextromethorphan, pseudoephedrine, to other nasal decongestants or any of the other ingredients of this medicine (listed in section 6).
- If you have a serious lung disease. If you have an asthmatic cough or a cough accompanied by abundant secretions.
- If you have severe high blood pressure (hypertension) or severe cardiovascular disease.
- If you have been diagnosed with hyperthyroidism.

- If you are being or have been treated in the last 2 weeks with:
  - any monoamine oxidase inhibitor (MAOI) used to treat depression, as it can cause an increase in blood pressure.
  - any medicine for Parkinson's disease or other diseases or with other serotonin reuptake inhibitors used to treat depression such as fluoxetine and paroxetine.
  - bupropion, a medicine used to give up smoking
  - linezolid, an antibacterial medicine (see section **Other medicines and cinfatos complex**).
- If you are pregnant and are in the first trimester of pregnancy

### Warnings and precautions

Do not exceed the dose recommended in section

### 3. How to take cinfatos complex.

Simultaneous use of this medicine with other medicines containing paracetamol should be avoided, since high doses may damage the liver. Do not use more than one medicine containing paracetamol without first consulting the doctor.

Taking cinfatos complex may cause sudden abdominal pain or rectal bleeding, due to inflammation of the colon (ischaemic colitis). If these gastrointestinal symptoms occur, stop taking cinfatos complex and contact your doctor or seek medical attention immediately. See section 4.

Reduction of blood flow to your optic nerve may occur with cinfatos complexe. If you develop sudden loss of vision, stop taking cinfatos complexe and contact your doctor or seek medical attention immediately. See section 4.

Talk to your doctor or pharmacist before taking **cinfatos complex** if you are a patient with:

- Kidney, liver, heart or lung disease or anaemia.
- Treatment with any medicine for epilepsy. Consult your doctor before taking this medicine as, when used at the same time, this decreases the efficacy and increases the hepatotoxicity of one of the active agents.
- Asthma that is sensitive to acetylsalicylic acid.
- Diabetes
- Cardiovascular disease, hypertension.
- High intraocular pressure (glaucoma).
- Difficulty urinating, urinary obstruction.
- Persistent or chronic cough, such as smoker's cough. Especially in children, chronic cough could be an early symptom of asthma.
- Atopic dermatitis (inflammatory disease of the skin characterised by rash, itching, exudation, scabs and desquamation which begins in childhood in individuals with hereditary allergic predisposition).
- Sedation or weakness or you are bedridden.
- Chronic alcoholics must be careful not to exceed the dose of this medicine recommended in section **3. How to take cinfatos complex**. If during the treatment you experience diarrhoea, stop taking this medicine immediately and consult your doctor.
- If you are taking other medicines such as antidepressants or antipsychotics, **cinfatos complex** can interact with these medicines and you may experience changes in your mental state (e.g. agitation, hallucinations, coma) and other effects such as a body temperature higher than 38°C, increased heart rate, arterial hypertension and exaggerated reflexes, muscle stiffness, lack of coordination and/or gastrointestinal symptoms (e.g., nausea, vomiting and diarrhoea).

Cases of abuse have been reported with medicines containing dextromethorphan in adolescents, so this possibility should be taken into account as it can cause serious side effects (see section If you take more cinfatos complex than you should).

If you are taking other medicines containing nasal decongestants, do not take this medicine.

Suspend treatment at least 24 hours before surgery.

Simultaneous use of cocaine and pseudoephedrine can increase the cardiovascular effects and risk of side effects.

### **Children and adolescents**

Do not administer this medicine to children under 12 years of age.

### **Elderly patients**

Elderly people are more prone to side effects, so it may be necessary to adjust the dose. Ask your doctor.

### **Other medicines and cinfatos complex**

Tell your doctor or pharmacist if you are taking, have recently taken or might have to take any other medicines.

In particular, if you are using any of the following medicines or substances with the pharmacological effect listed below, it may be necessary to modify the dose of some of them or discontinue treatment:

- Urinary alkalinising agents (sodium bicarbonate, citrates) as they can cause pseudoephedrine to be eliminated more slowly and increase its effect and its toxicity.
- Anaesthetics via inhalation as they can increase the risk of heart problems. Monoamine oxidase inhibitors (MAOI) used to treat depression (moclobemide, tranylcypromine, fluoxetine, paroxetine, bupropion), Parkinson's disease (selegiline) or other diseases, such as cancer (procarbazine), infections (linezolid, furazolidine). If you are being treated with any of them, the administration of each must be separated from the administration of **cinfatos complex** for a minimum of 15 days, both before and after. If it is not, as it contains pseudoephedrine, it could cause a severe increase in blood pressure, very high fever and headache.
- Medicines to treat depression and convulsions: barbiturates (used as hypnotics, sedatives and anticonvulsants).
- Medicines to treat epilepsy: anti-epileptics (lamotrigine, phenytoin or other hydantoin, phenobarbital, methylphenobarbital, primidone, carbamazepine).
- Levodopa (used for the treatment of Parkinson's disease) as it can increase the heart rhythm (arrhythmia).
- Nervous system stimulants (amphetamines, xanths) as they can cause nervousness, irritability, insomnia or possibly seizures or alterations of the heart rhythm (arrhythmia), as they can increase the effects of pseudoephedrine, causing a severe increase in blood pressure, very high fever and headache.
- Cocaine, which, in addition to stimulating the nervous system, using in conjunction with pseudoephedrine can increase the cardiac side effects.
- Central nervous system depressants (some of them used to treat mental illness, allergy, Parkinson's disease, etc).
- Some medicines for lowering blood pressure and treating alterations of the cardiac rhythm or to aid urine elimination (such as beta-blockers for example propanolol, ACE inhibitors, loop diuretics such as those of the furosemide group, Rauwolfia alkaloids such as reserpine, amiodarone and quinidine) as they can reduce the efficacy of these medicines.
- Digitalis glycosides (used for the heart) as they can cause alterations in the cardiac rhythm.
- Nitrates (used to treat angina pectoris), as the effects of the nitrates can be reduced.
- Medicines to prevent blood clots: oral anticoagulants (acenocoumarol, warfarin).
- Medicines used to lower blood cholesterol: cholestyramine.

- Thyroid hormones (used for thyroid disease) as the effects of both the hormones and pseudoephedrine can be increased.
- Medicines to treat tuberculosis: isoniazid, rifampicin.
- Medicines used to treat gout: probenecid and sulphapyrazole.
- Medicines used to prevent nausea and vomiting: metoclopramide and domperidone.
- Anti-inflammatory drugs: celecoxib, parecoxib or valdecoxib.
- Expectorants and mucolytics (used to eliminate sputum and mucus).

Do not take this medicine during treatment or in the 2 weeks after treatment with the following medications, as it may cause excitation, high blood pressure and fever above 40°C (hyperpyrexia):

- Monoamine oxidase inhibitors (MAOIs) (anti-depressants): moclobemide, tranylcypromine.
- Selective serotonin reuptake inhibitors (anti-depressants): paroxetine, fluoxetine
- Bupropion (used to stop smoking)
- Linezolid (used as an antibacterial)
- Procarbazine (used to treat cancer)
- Selegiline (used to treat Parkinson's disease)

### **Interferences with diagnostic tests**

If you are to undergo any tests (blood or urine tests, skin tests with allergens, etc.), tell your doctor that you are taking this medicine, because it may alter the results of such tests.

### **Cinfatos complex with food, drink and alcohol**

Alcoholic beverages should not be consumed during treatment with this medicine as it may cause severe side effects.

Do not take with grapefruit juice or bitter orange. Other food and drink does not affect the efficacy of the medicine.

### **Pregnancy and breast-feeding**

If you are pregnant or breastfeeding, suspect that you might be pregnant or intend to become pregnant, consult your doctor or pharmacist before taking this medicine.

**Cinfatos complex** is contraindicated during the first trimester of pregnancy, due to the presence of pseudoephedrine.

Paracetamol and pseudoephedrine enter breast milk and, therefore, breast-feeding women should ask their doctor or pharmacist before taking this medicine.

### **Driving and using machines**

Rarely during treatment, mild drowsiness and dizziness may appear, so if you observe the symptoms, you should not drive or use dangerous machines.

### **Cinfatos complex contains aspartame (E-951), maltitol (E-965), glycerol (E-422), methyl parahydroxybenzoate (E-219), propyl parahydroxybenzoate (E-217) and sodium citrate.**

This medicine may be harmful for people with phenylketonuria since it contains aspartame (E951), which is a source of phenylalanine.

This medicine contains maltitol (E-965). If you have been told by your doctor that you are intolerant to certain sugars, please talk to your doctor before taking this medicine.

This medicine may cause stomach problems and diarrhoea as it contains glycerol (E-422).

This medicine contains methyl (E-219) and propyl (E-217) sodium parahydroxybenzoate. This may cause allergic reactions (possibly delayed).

Athletes are informed that this medicine contains an ingredient that may yield a positive doping test result.

This medicinal product contains 19.5 mg sodium (the main component of table/cooking salt) in every 10 ml. This is equivalent to 1 % of the recommended maximum daily sodium intake for an adult.

### **3. How to take cinfatos complex**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Adults and adolescents aged over 12 years: one 10 ml measure, every 6-8 hours (3-4 times daily). Do not take more than 3 g of paracetamol every 24 hours (see section “Warnings and precautions”).

Patients with liver or kidney disease: must consult their doctor before taking this medicine. If your doctor prescribes this medicine for you, you must wait at least 8 hours between each dose.

Patients aged over 60: the dose should be decided by the doctor, since reducing the usual dosage may prove necessary in these patients.

#### Use in children and adolescents:

This medicine is indicated only in adolescents aged over 12. Children under 12 years of age must not take this medicine.

#### How to take cinfatos for children:

This medicine is taken orally.

Shake the bottle well before use.

Measure the amount of medicine to take in the dispensing cup that comes with the bottle. Wash the dispensing cup after use.

If you take the medicine at night, do so a few hours before going to bed, to reduce the possibility of insomnia in patients with difficulty sleeping.

This medicine should only be taken when symptoms are present. As the symptoms subside, the treatment should be discontinued.

If they increase, or if symptoms persist for more than 5 days (3 days for fever if any), or others appear such as high fever, skin rashes or persistent headache, consult your doctor.

#### **If you take more cinfatos complex than you should**

If you have taken more cinfatos complex than you should, you may experience symptoms such as dizziness, vomiting, loss of appetite, jaundice (yellow colouration of the skin) and abdominal pain. Seizures, difficulty breathing, hallucinations, increased blood pressure, irregular heartbeat, excitability, tremors, palpitations and difficulty urinating may also occur.

If you take more **cinfatos complex** than you should, you may experience the following symptoms: nausea and vomiting, involuntary muscle contractions, agitation, confusion, drowsiness, consciousness disorders, involuntary and quick eye movements, cardiac disorders (accelerated heart rhythm), co-ordination disorders, psychosis with visual hallucinations and hyperexcitability.

Other symptoms in the event of a massive overdose may be: coma, severe respiratory problems and seizures.

Contact your doctor or hospital immediately if you experience any of the aforementioned symptoms.

In case of overdose or accidental ingestion, notify your doctor or pharmacist immediately, specifying the medicine and the amount ingested.

In the event of overdose, quickly report to a medical centre even if there are no symptoms, since they often manifest themselves only after periods of up to three days, even in cases of severe overdose.

The period in which the management of overdose offers maximum efficacy is within four hours after taking the medicine.

Patients treated with barbiturates, or patients with chronic alcoholism, may be more susceptible to paracetamol overdose.

Cases of abuse have occurred with medicines containing dextromethorphan particularly in adolescents, and serious side effects can occur, including: anxiety, panic attacks, memory loss, tachycardia (accelerated heartbeat), lethargy, hypertension or hypotension (high or low blood pressure), mydriasis (dilated pupils), agitation, vertigo, gastrointestinal discomfort, hallucinations, slurred speech, nystagmus (uncontrolled, involuntary eye movement), fever, tachypnoea (fast, shallow breathing), brain damage, ataxia (uncoordinated movements), seizures, respiratory depression, loss of consciousness, arrhythmia (irregular heartbeat) and death.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody sees them.

Rare (may affect up to 1 in 1000 people):

- Malaise.
- Low blood pressure (hypotension).
- Increased transaminase levels in the blood.

Very rare side effects (may affect up to one in 10,000 people):

- Kidney disorders, turbid urine.
- Skin rashes with or without irritation, itching, inflammation of the skin (dermatitis), jaundice (yellowish colouration of the skin), severe skin reactions.
- Blood disorders (agranulocytosis, leukopenia, neutropenia, haemolytic anaemia) and hypoglycaemia (low blood sugar).

Side effects with unknown frequency (cannot be estimated from the available data):

- Altered heart rate (tachycardia, bradycardia and arrhythmias), palpitations, difficulty breathing (dyspnoea).
- Symptoms of excitation, sleep disorders, restlessness, dizziness, vertigo, headache, seizures, hallucinations and mental confusion. If you experience seizures or hallucinations, stop taking this medicine immediately.
- Involuntary closure of the eyelids (blepharospasm), phobia to light and watering eyes.
- Nausea, vomiting, gastrointestinal discomfort, inflammation of the bowel with frequent diarrhoea (ulcerative colitis) and constipation.
- Inflammation of the colon due to insufficient blood flow (ischaemic colitis).
- Urinary retention in men, pain or difficulty urinating.
- Tremor, paleness, weakness and increased sweating.
- Reduction of blood to the optic nerve (ischemic optic neuropathy).

Paracetamol may damage the liver when taken at high doses or during prolonged treatments.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store cinfatos complex**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the container after "EXP". The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. If unsure, ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### **6. Contents of the pack and other information**

What cinfatos complex contains

Each ml of oral suspension contains:

Paracetamol .....	50 mg
Dextromethorphan hydrobromide .....	2 mg
Pseudoephedrine hydrochloride .....	6 mg

The other ingredients (excipients) are: maltitol (E-965), glycerol (E-422), sodium citrate (E-331), citric acid monohydrate (E-330), hypromellose, xanthan gum, methyl parahydroxybenzoate (E-219), aspartame (E-951), ammonium glycerinate, propyl parahydroxybenzoate (E-217), orange flavour, orange juice flavour, masking flavour and purified water.

#### **What the product looks like and contents of the pack**

**Cinfatos complex** is a homogeneous ivory or camel suspension with an orange aroma that comes in amber glass bottles containing 125 ml of oral suspension. Each pack comes with a dispensing cup with marks corresponding to 2.5 ml, 5 ml, 7.5 ml, 10 ml and 15 ml.

#### **Marketing authorisation holder and manufacturer:**

LaboratoriosCinfa, S.A.  
Carretera Olaz-Chipi, 10. Polígono Industrial Areta.  
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